REMARKS

Upon entry of the above amendment, claims 1-7 and 9-14 are pending in this application. Applicant notes that the Examiner indicated in Paper No. 16 that claims 1-7, 9-11, 13 and 14 are allowed and only claim 12 remains rejected.

Applicant and the undersigned gratefully acknowledge the courtesy of the Examiner's telephone interviews of September 11 and 27, 1995.

The Examiner rejected claim 12 under 35 U.S.C. § 103, as allegedly unpatentable over Meyers. Applicant respectfully traverses the rejection.

According to the Examiner, Meyers discloses a large scale adaptation of a recently reported glycine precipitation method for the production of factor VIII:C concentrate that allegedly includes adding aluminum hydroxide to a glycine buffer to reduce the level of protein contamination in the final preparation, and that the resultant product was virus-inactivated by the incorporation of an organic solvent and detergent. The examiner further alleges that, at the industrial level, this method gave 185 IU of factor VIII:C activity per liter of starting plasma "which the Examiner deems to be at least equivalent to Applicants' yield." (Paper No. 16 at 2.) Thus, the Examiner concludes, the preparation of a solution with factor VIII:C activity containing a basic amino acid, such as glycine, and a nonionic detergent containing a high activity for clinical use would have been obvious. According to the Examiner, one of ordinary skill in the art would have been motivated to prepare a solution of factor VIII:C using Meyers' glycine precipitation method and therefore, claim 12 is not allowable.

As Applicant has previously stated, claim 12 is clearly nonobvious over Meyers. Meyers discusses a large scale adaptation of a glycine precipitation method for the production of factor VIII:C, which was virus inactivated by incorporation of organic solvent

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and detergent. The invention set forth in claim 12 is a process for the preparation of a stable factor VIII:C solution, which comprises adding an amino acid or one of its salts or homologs and an organic polymer or a detergent to a solution with factor VIII:C activity, wherein the specific factor VIII:C activity is at least 1,000 IU/mg. Quite simply, Meyers does not teach or suggest a stabilized solution having factor VIII:C wherein the specific factor VIII:C activity is at least 1,000 IU/mg.

The Examiner has stated that Meyers' method gave 185 IU of factor VIII:C activity per liter of starting plasma, "which the Examiner deems to be at least equivalent to Applicants' yield." (Paper No. 16 at 2, emphasis added.) First, the Examiner has not pointed to any evidence from the record to establish that 185 IU factor VIII:C per liter of starting plasma is equivalent to the specific factor VIII:C activity claimed in the present invention of at least 1,000 IU/mg. Applicant submits that it is unreasonable and scientifically untenable simply to "deem" one value "at least equivalent" to another without some basis for doing so. To the extent that this rejection is based upon facts within the personal knowledge of the Examiner, Applicant respectfully requests that the Examiner execute an affidavit under 37 C.F.R. § 1.107(b).

Second, Applicants respectfully submit that if the Examiner is going to compare values taken from Meyers with those in the present claims, then the Examiner must compare values having the same defined units; i.e., the Examiner should compare apples to apples. The Examiner has given no basis or reasoning to support the validity of comparing IU per liter starting plasma with IU/mg protein of the final product. Meyers simply does not suggest a stabilized factor VIII:C solution having a specific factor VIII:C activity that is even remotely close to the specific factor VIII:C activity recited in claim 12--at least 1,000 IU/mg. Moreover, Meyers is completely devoid of any teaching, suggestion

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or expectation that the specific factor VIII:C activity of the final solution is, or even could be, at least 1,000 IU/mg. Rather the final specific activity of Meyers' product is no higher than 4.4 ± 0.9 IU/mg protein.

In addition, the Examiner has stated that "one of ordinary skill in the art would have been motivated to prepare a solution of factor VIII:C using Meyers glycine precipitation method, and, therefore, the process claim, claim 12 is not allowable." (Paper No. 16 at 3.) Even assuming arguendo that one of skill in the art would be motivated to prepare a solution of factor VIII:C using Meyers' method, the skilled artisan would expect to produce a factor VIII:C solution having a specific factor VIII:C activity no greater than 4.4 ± 0.09 IU/mg. Meyers therefore lacks the requisite expectation of success. That is, Meyers offers no suggestion or teaching that would lead one skilled in the art to expect that Meyers' method would lead to a specific factor VIII:C activity of at least 1,000 IU/mg in the final product.

Moreover, in determining whether the subject matter of claim 12 would have been obvious, the Examiner must consider all limitations of the claims. See In re Ochiai, 37 U.S.P.Q.2d 1127, 1131 (Fed. Cir. 1995). Furthermore, as the Examiner is aware, the MPEP clearly states that the cited art "must teach or suggest all the claim limitations." M.P.E.P. § 706.02(j). In this instant case, the Examiner must consider all limitations in claim 12, including that the final specific factor VIII:C activity is at least 1000 IU/mg. Myers simply does not teach or suggest a process leading to a stable factor VIII:C solution having the activity set forth in claim 12.

For all the above reasons, and for the reasons set forth in the Amendment of August 24, 1995, the rejection is in error and should be withdrawn.

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Applicants note that the Examiner indicated that claims 1-7 and 9-11, and 13-14 are allowable. However, Applicants respectfully submit that all claims now pending in this application, i.e., claims 1-7 and 9-14 are in condition for allowance. Applicants therefore respectfully request that the Examiner promptly issue a Notice of Allowance.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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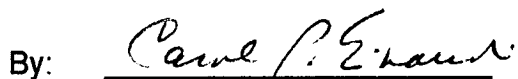
By: 
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